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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,330	09/01/2005	Hirofumi Nakamura	Q89815	7031
23373 7590 12/10/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
PAGE, BRENT T				
ART UNIT		PAPER NUMBER		
1638				
MAIL DATE		DELIVERY MODE		
12/10/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/547,330

Applicant(s)

NAKAMURA ET AL.

Examiner

BRENT PAGE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Reply filed by Applicants on 08/07/2008 is hereby acknowledged. The cancellation without prejudice of claims 2-4, 7-9 and 13-20 is hereby acknowledged. Any objection or rejection of record not addressed below is considered to be hereby withdrawn in response to Applicant's arguments when taken together with the claim amendments filed on 08/07/2008.

Claim Rejections - 35 USC § 112-enablement

Claims 1, 5, 6, and 10-12 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the transformation of *Nicotiana* or *Beta vulgaris* with SEQ ID NO:1, does not reasonably provide enablement for the transformation of any plant with any beta-fructofuranosidase from any source, or even any plant with any variant of SEQ ID NO:1 as broadly claimed wherein sucrose would be converted into an fructooligosaccharide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims remain rejected for the reasons of record as well as the reasons set forth below.

Applicant's arguments filed 08/07/2008 have been fully considered but they are not persuasive.

Applicants urge that the specification provides guidance for variants of SEQ ID NO:1 on pages 7-8 of the specification and that the Office Action recognizes that the present specification provides guidance for variants of beta-fructofuranosidase derived from *Aspergillus niger* (pages 6-7 of response).

This is not persuasive because the office action recognizes only SEQ ID NO:1 and does not acknowledged any variants of the sequences are taught by the specification. Furthermore, the general teachings of pages 7-8 of the specification, do not guide one as to what regions and areas of the sequence may be altered to retain function. The specification does not provide guidance as to which sequences are necessary for the function and therefore does not provide guidance for one of skill in the art to fully recognize all enabled embodiments, nor does the specification give any guidance or indication that any other embodiments other than SEQ ID NO:1 are even enabled. The art cited demonstrates the unpredictability of altering the sequences of such genes and therefore, guidance is required for one of skill in the art to obtain functioning variants of the gene as broadly claimed.

Claim Rejections - 35 USC § 112-written description

Claims 1, 5-6, and 10-12 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims remain rejected for the reasons of record as well as the reasons set forth below.

Applicant's arguments filed 08/07/2008 have been fully considered but they are not persuasive.

Applicants urge that both claim amendments and the specification, particularly pages 7-8 provide sufficient written description for the full scope of the claims (page 7-8 of response).

This is not persuasive because Applicants have only demonstrated that SEQ ID NO:1 functions as a beta-fructofuranosidase. Applicants have not provided any other working examples. In the absence of working examples, Applicants are required to disclose which structural features are required for the claimed function. Applicants have not described which of the structural features of SEQ ID NO:1 are required for this function. Accordingly, one of skill in the art does not have a full description of the embodiments over the full scope of the claims.

Claim Rejections - 35 USC § 112-2nd paragraph indefinite

Claims 1, 5-6 and 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as amended recites a nucleotide sequence having a 85% or more "homology" with that of SEQ ID NO:1.

The term "homology" is only defined as "a value obtained by a known program for a homology search". It remains unclear what is meant by homology. Submitting an algorithm by BLAST does not clarify the claims as amended because neither the specification nor the claims limit homology to homology as defined by BLAST. The state of the art recognizes several different definitions for homology and homology may be based on conserved amino acids, or even

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conservative substitutions. Because of the multiple definitions, it is unclear exactly what is meant by homology.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-6 and 10-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Smeekens et al (WO199601904) in view of Yanai et al (US Patent 6337201) for the reasons of record, as well as the reasons set forth below.

Applicant's arguments filed 08/07/2008 have been fully considered but they are not persuasive.

Applicants urge that the Office Action has not provided a rational reason for one skilled in the art to modify the transformation disclosed by Smeekens et al with the beta-fructofuranosidase gene of Yanai et al (page 10 of response).

This is not persuasive as both Smeekens et al and Yanai et al provide motivation for such a modification of the transformation by Smeekens et al.

Firstly, as mentioned in the office action, Smeekens et al compares the sequences of several sources fructosyl genes including bacterial and fungal sources. The aim of Smeekens et al was the modification of sugar content in plants, the same goal as the instant invention. Smeekens et al recognizes

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multiple genes may be used for the sugar content modification. One further would have been motivated by the annotation of Yanai et al that states the disclosed gene is "useful for the conversion of sugars, e.g. sucrose to fructo-oligosaccharide such as 1-ketose". The recognition by Smeekens of using bacterial and fungal genes in plants for modifying sugar content combined with the teaching of Yanai et al over the usefulness of the disclosed gene renders the instant claim as obvious over the said teachings.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Russell Kallis/
Primary Examiner, Art Unit 1638